

FEB 27 2004

510(k) Summary of Safety and Effectiveness: k040129

SPONSOR:	Wilson-Cook Medical 4900 Bethania Station Road Winston-Salem, NC 27105
CONTACT/SUBMITTER:	Marge Walls-Walker Regulatory Affairs Specialist [336] 744-0157 Ex.290
DATE OF SUBMISSION:	February 13, 2004
DEVICE:	Tri-Ex Extraction Balloon with Multiple Sizing
Trade Name:	Tri-Ex Extraction Balloon with Multiple Sizing
Common Name:	Extraction Balloon
Classification:	Catheter, Biliary, Surgical, Class II 21 CFR § 876.5010 78 GCA
PREDICATE DEVICES:	Wilson-Cook Triple Lumen Balloon Stone Extractor (k953951)
INTENDED USE:	Wilson-Cook's Tri-Ex Extraction Balloon with Multiple Sizing is for endoscopic removal of stones in the biliary system and for contrast injection.
DEVICE DESCRIPTION:	The proposed Extraction Balloon is a modification to existing extraction balloons currently marketed by Wilson-Cook. The Tri-Ex Extraction Balloon with Multiple Sizing is supplied sterile and intended for single use only.
COMPARISON OF CHARACTERISTICS:	We believe the proposed device to be substantially equivalent to currently marketed Wilson-Cook biliary extraction balloons as cleared by k953951
PERFORMANCE DATA:	We believe the proposed device to be substantially equivalent to the named predicate in terms of Intended Use, performance characteristics tested and biocompatibility.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marge Walls-Walker
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K040129

Trade/Device Name: Wilson-Cook Tri-Ex Extraction Balloon with Multiple Sizing
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 GCA
Dated: February 13, 2004
Received: February 17, 2004

Dear Ms. Walls-Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040129

Device Name: Wilson-Cook Tri-Ex Extraction Balloon with Multiple Sizing

Indications for Use:

The Tri-Ex Extraction Balloon with Multiple sizing is used for endoscopic removal of stones in the biliary system and for contrast injection.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE-IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ☒
(Per 21 CFR § 801.109)

OR

Over-the-Counter ☐

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040129